#### UNITED STATES DISTRICT COURT - WESTERN DISTRICT OF TENNESSEE

MEGAN KETTNER and DONALD JUENGLING,		
Plaintiffs,	Docket No.:	
•	Docket No.:	
v.		JURY DEMANDED
CADISTA HOLDINGS, INC. and		
JUBILANT CADISTA		
PHARMACEUTICALS, INC.,		
Defendants.		

COMPLAINT FOR COMPENSATORY AND PUNITIVE DAMAGES
RELATED TO PRODUCTS LIABILITY, NEGLIGENCE,
BREACH OF IMPLIED WARRANTY, BREACH OF EXPRESS WARRANTY,
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS, LOSS OF CONSORTIUM,
FRAUD, and NEGLIGENT MISREPRESENTATION

COME NOW Plaintiffs Megan Kettner and Donald Juengling (Plaintiffs), by and through counsel, seeking Compensatory and Punitive Damages Related to Products Liability, Negligence, Breach of Implied Warranty, Breach of Express Warranty, Negligent Infliction of Emotional Distress, Loss of Consortium, Fraud, and Negligent Misrepresentation on the part of these Defendants.

Plaintiffs would show unto the Court as follows:

#### **PARTIES**

1. Plaintiff MEGAN KETTNER ("Ms. Kettner" or "Plaintiff") is a citizen and resident of the State of Tennessee.

- 2. Plaintiff DONALD JUENGLING ("Mr. Juengling" or "Plaintiff's husband") is a citizen and resident of the State of Tennessee.
- In June 2018, Ms. Kettner was prescribed and used the product Methylprednisolone
   as designed, tested, manufactured, marketed, distributed and/or sold by Defendants.
- 4. Defendants CADISTA HOLDINGS INC. ("Holdings") is a corporation based in Noida, India, and is engaged in the manufacture, sale, and distribution of prescription pharmaceutical products.
- 5. Defendants JUBILANT CADISTA PHARMACEUTICALS, INC., ("Jubilant") is a wholly-owned subsidiary of Defendants Holdings, with its principal place of business located at 207 Kiley Drive, Salisbury, Maryland, 21801.

## **JURISDICTION AND VENUE**

- 6. This Court has subject matter jurisdiction pursuant to 18 U.S.C. § 1964(c), 28 U.S.C. §§ 1331 (federal question) and 1337 (acts regulating commerce), pursuant to 28 U.S.C. §1332 (diversity of citizenship) because the matter in controversy exceeds the sum or value of \$75,000 exclusive of interest and costs and is between citizens of different states, and pursuant to 28 U.S.C. § 1367 (supplemental jurisdiction).
- 7. Venue in this district is proper pursuant to 28 U.S.C. § 1391 and 18 U.S.C. § 1965(a), in that one of both Defendants do business in this district, and because a substantial part of the events or omissions giving rise to the claims occurred in this district.

## **FACTS**

- 8. Defendants have marketed, distributed, and sold Methylprednisolone to millions of Americans including Ms. Kettner. <u>See package insert, enclosed as Exhibit 1</u>.
  - 9. Methylprednisolone is a glucocorticoid / corticosteroid. <u>Id</u>.

- 10. Psychic derangements may appear when Methylprednisolone is used, ranging from euphoria, insomnia, mood swings, personality changes, severe depression even frank psychotic manifestations. <u>Id</u>.
- 11. Severe reactions to corticosteroid therapy are common with severe reactions occurring in nearly six-percent (6%) of patients. See "Psychiatric Adverse Effects of Corticosteroids", Warrington, T.P. and Michael Bostwick, M.D., Mayo Clinic Proc., (October 2006), attached as Exhibit 2.
- 12. The neuropsychiatric adverse effects of corticosteroids are complex, unpredictable, and often severe, ranging across most categories of psychopathology. <u>Id</u>. (Internal citations omitted).
- 13. Severe episodes of corticosteroid-induced psychiatric disturbances involve depression, mania, or psychosis and frequently include suicidal ideation. <u>Id</u>.
- 14. On June 7, 2018, Plaintiff Megan Kettner presented to her local clinic with poison ivy.
- 15. Ms. Kettner was prescribed Methylprednisolone, and received and began a weeklong regimen of Defendants' Methylprednisolone product.
- 16. On or about June 14, 2018, Ms. Kettner began a second round of defendants' Methylprednisolone product.
- 17. On June 18, 2018, Defendant Donald Juengling began to notice significant changes in his wife Megan's behavior and mood.
- 18. On June 19, 2018, Mr. Juengling noted that Ms. Kettner's behavior was becoming increasingly erratic, argumentative, and irrational.

- 19. On June 19 and June 20, 2018, Ms. Kettner suddenly became very quiet, dissociated, and non-communicative.
- 20. Mr. Juengling arrived home from work on June 22, 2018 to find his wife unconscious and barely breathing, and all their pets dead -- locked in her car with the motor running, tubing running from the tailpipe to a cracked window.
- 21. Mr. Juengling broke a window of the car, dragged his wife from the vehicle, and called 9-1-1.
- 22. After Ms. Kettner was transported to the hospital, the police questioned Mr. Juengling, at length as if he were a suspect in an attempted homicide.
- 23. Ms. Kettner spent approximately five days in St. Francis Hospital, a portion thereof in an unresponsive coma.
- 24. After arousal from her coma, Ms. Kettner did not recognize her husband at all, would not uncurl from the fetal position, and would only repeat: "Mama! Mama!", over and over again.
- 25. During her hospitalization, Ms. Kettner's treating physicians were pessimistic as to whether she would recover any or all of her higher cognitive function.
- 26. Given Ms. Kettner's attempted suicide, she spent the next approximately six days in a local psychiatric facility, Lakeside Hospital.
- 27. Mr. Juengling and Ms. Kettner are currently receiving significant counseling related to the traumatic death of their beloved pet "children".
- 28. All plans for having children of their own has been suspended, possibly terminated.

- 29. Defendants' Methylprednisolone product was a but-for cause of Plaintiff Kettner's suicide attempt, and a proximate cause of her subsequent medical hospitalization, psychiatric hospitalization, and ongoing treatment and other damages.
- 30. Defendants' Methylprednisolone product was a proximate cause of Plaintiff Juengling's emotional distress, loss of consortium, and other damages.

### **COUNT I – PRODUCTS LIABILITY**

- 31. Defendants designed, developed, tested, manufactured, marketed, distributed and/or sold Methylprednisolone.
- 32. Methylprednisolone was mislabeled regarding the actual active ingredient, prescription strength corticosteroids, and was not accompanied by adequate warnings regarding the potential adverse side effects associated with the use of corticosteroids.
- 33. Methylprednisolone was defective due to the Defendants' failure to warn Ms. Kettner that Methylprednisolone contained corticosteroids and about the potential adverse side effects associated with the use of corticosteroids.
- 34. Methylprednisolone as designed, developed, tested, manufactured, distributed, marketed and/or sold by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or sellers, the foreseeable risks exceeded the benefits associated with the design formulation.
- 35. Alternatively, Methylprednisolone as designed, developed, tested, manufactured, distributed, marketed and/or sold by Defendants was defective in design or formulation, in that when it left the hands of the manufacturer and/or sellers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect, and it was more dangerous than it was represented to be by the Defendants.

- 36. Methylprednisolone as designed, developed, tested, manufactured, distributed, marketed and/or sold by Defendants was defective due to inadequate warnings because Defendants knew or should have known that Methylprednisolone contained corticosteroids that created a risk of harm to consumers, and the Defendants failed to adequately warn of the risks of corticosteroid use.
- 37. Methylprednisolone as designed, developed, tested, manufactured, distributed, marketed and/or sold by Defendants was defective due to inadequate post-marketing warnings because, after the Defendants knew or should have known of the risk of injury from use of Methylprednisolone, they failed to provide adequate warnings to users or consumers of the product.
- 38. Defendants jointly and severally are strictly liable to Ms. Kettner under Restatement (Second) of Torts § 402A for the harm, damages and injuries complained of herein by reason of having sold and placed into the stream of commerce a defective product that was unreasonably dangerous to consumers and by failing to warn Ms. Kettner of the adverse health risks associated with the use of Methylprednisolone.
- 39. As a direct and proximate result of Defendants' defective product or failure to warn of latent dangers in the product's use, as described herein, Ms. Kettner was caused to suffer substantial and severe harm, injury and damage.

## **COUNT II – NEGLIGENCE**

- 40. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:
- 41. Defendants had a duty to exercise reasonable care in the design, development, testing, manufacture, distribution, marketing and/or sale of Methylprednisolone.

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- 42. Defendants failed to exercise reasonable care in the design, development, testing, manufacture, distribution, marketing and/or sale of Methylprednisolone by reason of at least the following acts and omissions:
  - a. Defendants' failure to design and/or manufacture Methylprednisolone that would not injure its users;
  - b. Defendants' failure to timely and adequately warn of dangerous side effects of the use of Methylprednisolone; and
  - c. Defendants' otherwise failing to exercise due care under the circumstances.
- 43. Defendants knew or should have known that Ms. Kettner and other Methylprednisolone users could suffer injury from use of Methylprednisolone as the result of their failure to exercise reasonable care.
- 44. As direct and proximate cause of Defendants' negligence, Ms. Kettner was caused to suffer substantial and severe harm, injury and damage.

## **COUNT III – BREACH OF IMPLIED WARRANTY**

- 45. Plaintiff incorporate by reference all preceding paragraphs as if fully set forth herein, and further allege as follows:
- 46. Defendants impliedly warranted to Ms. Kettner that Methylprednisolone, which they designed, developed, tested, manufactured, marketed, distributed, and/or sold, was of merchantable quality, fit and safe for its ordinary and reasonably foreseeable purpose and not otherwise injurious to Ms. Kettner's health and well-being, and that Methylprednisolone conformed to the promises or affirmations of fact made on the container or label.
- 47. As set forth above, Methylprednisolone was unfit and unsafe for its ordinary purpose, unmerchantable, unfit for use and was otherwise injurious to Ms. Kettner, and did not conform to the promises or affirmations of fact made on the container or label.

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- 48. Through their sale of Methylprednisolone, Defendants are "merchants" pursuant to the Tennessee enactment of the Uniform Commercial Code.
- 49. Defendants breached the implied warranty of merchantability in the sale of Methylprednisolone in that it was not fit for its ordinary and reasonably foreseeable purpose because of its defective and unreasonably dangerous condition as set forth above, and did not conform to the promises or affirmations of fact made on the container or label.
- 50. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability as described herein, Ms. Kettner was caused to suffer substantial and severe harm, injury and damage.

#### COUNT IV - BREACH OF EXPRESS WARRANTY

- 51. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:
- 52. Defendants expressly warranted, directly or indirectly, to Ms. Kettner that Methylprednisolone was of merchantable quality and safe for its normal and foreseeable use.
- 53. Methylprednisolone was unmerchantable and unsafe for use because its active ingredient was corticosteroids, a prescription drug with serious potential adverse side effects.
- 54. At the time of making the express warranties, Defendants had knowledge of the purpose for which their product was to be used.
- 55. Ms. Kettner relied on the express warranties and representations of Defendants in purchasing and using Methylprednisolone.
- 56. Defendants breached the above-mentioned warranties because Methylprednisolone is and was unsafe for its foreseeable use because it did and does contain corticosteroids and did and can cause attendant medical problems as described herein.

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57. As a direct and proximate result of Defendants' breach of express warranties as described herein, Ms. Kettner was caused to suffer substantial and severe harm, injury, and damage.

# COUNT V – NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS / LOSS OF CONSORTIUM

- 58. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:
- 59. Defendants placed Methylprednisolone into the stream of commerce and misrepresented that it was safe for consumption, when they knew or should have known that it contained corticosteroids, a powerful prescription medication, as its active ingredient or were reckless in not knowing that it contained corticosteroids.
- 60. Defendants placed Methylprednisolone into the stream of commerce without reasonable or adequate testing.
- 61. Defendants placed Methylprednisolone into the stream of commerce without adequate warnings and/or labeling, and then failed to issue adequate and necessary warnings after the significant negative physical and psychological sequellae from corticosteroid use was discovered, documented, and acknowledged.
- 62. Plaintiffs sustained severe emotional distress and Loss of Consortium as a result of Defendants' conduct.
  - 63. Ms. Kettner sustained physical injures as a result of Defendants' conduct.

#### COUNT VI - FRAUD

- 64. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:
- 65. Defendants made false and misleading representations to Ms. Kettner and other Methylprednisolone users about the active ingredient in Methylprednisolone.
- 66. The representations made by Defendants were false and misleading and were of a fraudulent and deceptive nature.
- 67. Defendants knew, or should have known, that their representations and omissions were misleading when made. Defendants made false and misleading representations to Ms. Kettner with the intent to deceive and to obtain money from her by the false representations and omissions.
- 68. Ms. Kettner reasonably and justifiably relied on Defendants' false and misleading representations and omissions, which led her to purchase Methylprednisolone.
- 69. By reason of Defendants' fraudulent misrepresentations and omissions, Ms. Kettner was caused to suffer substantial and severe harm, injury and damages.
- 70. The conduct of Defendants in perpetrating the fraud described above was malicious, willful, wanton, and oppressive, or in reckless disregard of the rights of Ms. Kettner who purchased Methylprednisolone, warranting the imposition of punitive damages against Defendants.

## <u>COUNT VII – NEGLIGENT MISREPRESENTATION</u>

- 71. Plaintiff incorporates by reference all preceding paragraphs as if fully set forth herein and further alleges as follows:
- 72. Defendants had a duty to inform Ms. Kettner truthfully and accurately about the actual active ingredient in Methylprednisolone.

- 73. Defendants negligently or recklessly supplied misleading information to Ms. about the active ingredient in Methylprednisolone, in order to induce Ms. Kettner to purchase Defendants' product.
  - 74. Ms. Kettner reasonably relied on Defendants' misleading information.
- 75. By reason of Defendants' negligent or reckless misrepresentations and omissions, Ms. Kettner was caused to suffer substantial and severe harm, injury and damages.

## PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiffs pray for judgment against Defendants as follows:

- a. That judgment be entered for Ms. Kettner and against Defendants for compensatory damages in an amount not to exceed \$5,000,000;
- b. That judgment be entered for Plaintiffs and against Defendants for threefold the amount of compensatory damages awarded, together with the costs of this action, including reasonable attorneys' fees; and
- c. For all other relief that these Plaintiffs may be entitled to at equity or at law and as this Court deems just, necessary and proper.

The Plaintiffs hereby demand a trial by a jury of twelve persons, as provided in Federal Rules of Civil Procedure Rule 38(b) and Rule 48(a).

# **Affidavit**

My name is Donald Juengling, and the facts and allegations represented herein have been rendered in true and accurate form, as I understand them.

Donald Juengling

8.27.18

Date

Notary Public

My commission xpires

TENNESSEE
NOTARY
PUBLIC

# **Affidavit**

My name is Megan Kettner, and the facts and allegations represented herein have been rendered in true and accurate form, as I understand them.

Megan Kettner

8/27/18

Date

Notary Public

My commission expires

Respectfully submitted,

MITCHELL LAW FIRM LLC

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